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PATENT LEGAL DEPARTMENT/A-42-C  
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EXAMINER

COURSON, TANIA C

ART UNIT PAPER NUMBER

2859

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/060,751

Applicant(s)

MC NEAL ET AL.

Examiner

Tania C. Courson

Art Unit

2859

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "no layer of cells" as stated in line 1 of claim 25 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "239" has been used to designate both "visible light beam" on page 4, line 28, and "cap" on page 7, line 18. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites on lines 4-5 "substantially blocked by cells" which signifies the

cells are being claimed as part of the invention. Claim 25, line 1, states "the container contains no layer of cells", thus removing the cells from the invention, this claim language is confusing. Neither the specification nor the drawings support "no cells" as part of the invention.

5. With respect to claim 25: the prior art of record has not been applied to claim 25 due to the confusing description as stated above in paragraph 4.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 4-8, 10-13, 17-18, 22-24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Cadell et al. (US 6,195,158 B1).

Cadell et al. disclose in Figures 1-4, an apparatus and method for a blood analyzer comprising:

With respect to apparatus claims 22 and 26 and method claims 1, 12, 18 and 23 comprising the steps of:

a) projecting onto the container a first detecting light beam/source of visible light

(Fig. 1, LEDs 16) that is substantially transmitted by serum, plasma and a material

Art Unit: 2859

- but substantially blocked by cells, a portion of the first detecting light beam being transmitted through the container (column 3, line 66 through column 4, line 14);
- b) projecting onto the container a second detecting light beam/source of infrared light (Fig. 1, LEDs 16) that is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material, a portion of the second detecting light beam being transmitted through the container (column 3, line 66 through column 4, line 14);
  - c) detecting, with a first detector (Fig. 1, detectors 20), as a function of position along the vertical axis of the container, the portion of the first detecting light beam that is transmitted through the container and no significant portion of the second detecting light beam (column 3, line 66 through column 4, line 14);
  - d) detecting, with a second detector (Fig. 1, detectors 20), as a function along the vertical axis of the container, the portion of the second detecting light beam that is transmitted through the container and no significant portion of the first detecting light beam (column 3, line 66 through column 4, line 14), and;
  - e) determining, with a processor, the location of at least one interface from the detected portions (column 3, line 66 through column 4, line 14);

With respect to claim 4:

- a) wherein the container is a test tube (Fig. 1, tube 22);

With respect to claim 5:

Art Unit: 2859

- a) wherein the container contains an upper layer of plasma or serum, and a lower layer of cells (Fig. 1);

With respect to claim 6:

- a) wherein a plurality of labels are on the container (column 2, lines 2-4 and lines 46-48);

With respect to claim 7:

- a) wherein the first and second detecting light beams are projected by a projector and detected by detector and wherein the projector and detector are substantially aligned so that the light beams strike the container substantially perpendicular to the axis of the container (Fig. 1);

With respect to claims 8 and 13:

- a) wherein the container further contains a middle layer of gel between the layer of serum or plasma and the layer of cells, and both light beams are substantially transmitted by the gel (Fig. 1, gel 26);

With respect to claim 10:

- a) wherein the light beams are projected by a laser (Fig. 3, laser 28);

With respect to claim 11:

Art Unit: 2859

- a) wherein the light beams are projected by fiber optic (Fig. 2, fiber optic 10);

With respect to claim 17:

- a) wherein the container has at least one label on its exterior that obscures at least one interface (column 2, lines 2-4 and lines 46-48);

With respect to claim 24:

- a) wherein the location of the interface that is determined is the location between air and the contents of the container (Fig. 1);

8. Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Kawano (US 2002/0067476 A1).

Kawano discloses in Figure 1, an analytical method for blood comprising:

With respect to method claim 1 comprising the steps of:

- a) projecting onto the container a first detecting light beam (Fig. 1, optical fiber 7) that is substantially transmitted by serum, plasma and a material but substantially blocked by cells, a portion of the first detecting light beam being transmitted through the container (paragraph 33, line 6 through paragraph 34, line 5);
- b) projecting onto the container a second detecting light beam (Fig. 1, optical fiber 7) that is substantially blocked by serum, plasma, and cells, but is substantially transmitted by the material, a portion of the second detecting light beam being

Art Unit: 2859

transmitted through the container (paragraph 33, line 6 through paragraph 34, line 5);

- c) detecting (Fig. 1, optical sensor within apparatus 1), as a function of position along the vertical axis of the container, the portion of the first detecting light beam that is transmitted through the container and no significant portion of the second detecting light beam (paragraph 30, lines 4-9);
- d) detecting (Fig. 1, optical sensor within apparatus 1), as a function along the vertical axis of the container, the portion of the second detecting light beam that is transmitted through the container and no significant portion of the first detecting light beam (paragraph 30, lines 4-9), and;
- e) determining the location of at least one interface from the detected portions (Fig. 1, computer 2 and paragraph 36, line 1-5);

With respect to claim 9:

- a) wherein a cap is covering the container (Fig. 1, cap 6).

*Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



10. Claims 2-3, 14-16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cadell et al.

Cadell et al. disclose an apparatus and method for a blood analyzer, as stated above in paragraph 7.

Cadell et al. do not disclose wherein a material is plastic, a material is glass, wherein the wavelength of the first light beam is from about 300 nm to about 1200nm, wherein the wavelength of the second light beam is from about 1.4  $\mu\text{m}$  to about 2.8  $\mu\text{m}$ , wherein the wavelength of the second light beam is from about 3.8  $\mu\text{m}$  to about 6.8  $\mu\text{m}$

Regarding claims 2-3: Cadell et al. disclose the test tube (tube 22) made of a material. The particular type of material used to make the test tube, absent any criticality, is only considered to be the use of a "preferred" or "optimum" material out of a plurality of well known materials that a person having ordinary skill in the art at the time the invention was made would have find obvious to provide using routine experimentation based, among other things, on the intended use of Applicant's apparatus, i.e., suitability for the intended use of Applicant's apparatus. See In re Leshin, 125 USPQ 416 (CCPA 1960 ) where the court stated that a selection of a material on the basis of suitability for intended use of an apparatus would be entirely obvious.

Regarding the wavelength of the first light beam and the second light beam: Cadell et al. discloses different wavelengths (column 3, lines 23-35) but does not disclose a particular value for this parameter. However, it would have been obvious to a person having ordinary skill in the

Art Unit: 2859

art at the time the invention was made to provide a wavelength of the first light beam from about 300 nm to about 1200nm, a wavelength of the second light beam from about 1.4  $\mu\text{m}$  to about 2.8  $\mu\text{m}$ , the wavelength of the second light beam from about 3.8  $\mu\text{m}$  to about 6.8  $\mu\text{m}$ , since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the "optimum range" involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### *Conclusion*

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The prior art cited on PTO-892 and not mentioned above disclose a blood analyzing method and apparatus:

Cole et al. (US 6,446,515 B2)

Vogler et al. (US 5,547,577)

Wieniowski (US 4,350,441)

Cullis (US 4,303,336)

Hirschfeld (US 4,100,416)

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tania C. Courson whose telephone number is (703) 305-3031.

The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM.

Art Unit: 2859

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez, can be reached on (703) 308-3875. The fax number for this Organization where this application or proceeding is assigned is (703) 308-7724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.



DIEGO F.F. GUTIERREZ  
SUPERVISORY PATENT EXAMINER  
GROUP ART UNIT 2859

TCC  
April 4, 2003